



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,728	07/21/2006	Bertram Jacobs	01231.0023U2	1957
23859 7590 03/02/2007 NEEDLE & ROSENBERG, P.C. SUITE 1000 999 PEACHTREE STREET ATLANTA, GA 30309-3915			EXAMINER WHITEMAN, BRIAN A	
			ART UNIT 1635	PAPER NUMBER

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	03/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/563,728

Applicant(s)

JACOBS ET AL.

Examiner

Brian Whiteman

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-16 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                          |

**DETAILED ACTION**

Claims 1-16 are pending.

***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-10, drawn to a method of using a vaccinia virus having an inactivation mutation in an interferon resistance gene.

Group II, claim(s) 11-16, drawn to a vaccinia virus having an inactivation mutation in an interferon resistance gene.

The inventions listed as Groups I-II do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons:

37 CFR 1.475(b) states:

“An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

37 CFR 1.475(c) states:

“If an application contains claims to more or less than one of the combination of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.”

37 CFR 1.475(d) also states:

“If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 1.476(c).”

37 CFR 1.475(e) further states:

“The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternative within a single claim.”

In view of 37 CFR 1.475 (b), 37 CFR 1.475 (c), 37 CFR 1.475 (d), and 37 CFR 1.475 (e), Group I is considered the main invention to the product first mentioned in the claims, and the

first recited invention drawn to other categories related thereto, e.g. a method of making, method of use.

The technical feature linking groups I-II appears to be a vaccinia virus having an inactivation mutation in an interferon resistance gene.

However, Lee (Virology 199: 491-496, 1994) teaches the vaccinia virus (cited on an IDS, PTO-1449).

Therefore, the technical feature linking the inventions of groups I-II does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

The special technical feature of Group I is considered to be a method of using a vaccinia virus having an inactivation mutation in an interferon resistance gene.

The special technical feature of Group II is considered to be a vaccinia virus having an inactivation mutation in an interferon resistance gene.

Accordingly, Groups I-II are not so linked by the same or a corresponding technical feature as to form a single general inventive concept.

If applicant elects Group I or II, applicant is further required to elect a species.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Group I:

a) wherein the inactivating mutation is in a gene selected from the group consisting of E3L, K3L, or a combination thereof; and

**Group II:**

b) wherein the inactivating mutation is in a gene selected from the group consisting of E3L, K3L, or a combination thereof.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

**Group I:**

The claims are deemed to correspond to the species listed above in the following manner:

a) claims 4-7

**Group II:**

The following claim(s) 1 is generic.

b) claims 13-16;

The following claim(s) 11 and 12 are generic.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: a) each inactivation has a distinct structure and b) each inactivation has a distinct structure.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and

Art Unit: 1635

specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 6:30 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Douglas Schultz, PhD, SPE - Art Unit 1635, can be reached at (571) 272-0763.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of



Application/Control Number: 10/563,728

Page 8

Art Unit: 1635

such papers must conform with the notice published in the Official Gazette, 1096 OG 30

(November 15, 1989). The Fax Center number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Brian Whiteman



## Electronic Acknowledgement Receipt

<b>EFS ID:</b>	1739387
<b>Application Number:</b>	10563728
<b>International Application Number:</b>	
<b>Confirmation Number:</b>	1957
<b>Title of Invention:</b>	<p>Mutants of vaccinia virus as oncolytic agents</p> <div style="text-align: right; border: 1px solid black; padding: 5px; margin-top: 10px;"> <p style="text-align: center;">Needle &amp; Rosenberg</p> <p>By <u>10/1</u> DOCKETED Date <u>05/03/2007</u></p> <p>Reviewed _____ Name/Date _____</p> <p>Scanned _____</p> </div>
<b>First Named Inventor/Applicant Name:</b>	Bertram Jacobs
<b>Customer Number:</b>	23859
<b>Filer:</b>	P. Brian Giles
<b>Filer Authorized By:</b>	
<b>Attorney Docket Number:</b>	01231.0023U2
<b>Receipt Date:</b>	02-MAY-2007
<b>Filing Date:</b>	21-JUL-2006
<b>Time Stamp:</b>	20:09:03
<b>Application Type:</b>	U.S. National Stage under 35 USC 371

### Payment information:

Submitted with Payment	yes
Payment was successfully received in RAM	\$60
RAM confirmation Number	1205
Deposit Account	

### File Listing:

Document Number	Document Description	File Name	File Size(Bytes)	Multi Part / .zip	Pages (if appl.)
-----------------	----------------------	-----------	------------------	-------------------	------------------

1	Extension of Time	01231_0023U2_2007_05_02 _Request_EOT.PDF	55904	no	2
---	-------------------	---	-------	----	---

**Warnings:**

**Information:**

2		01231_0023U2_2007_05_02 _Response_Restriction_Req uirement.PDF	126508	yes	5
---	--	--	--------	-----	---

	<b>Multipart Description/PDF files in .zip description</b>				
	<b>Document Description</b>		<b>Start</b>	<b>End</b>	
	Response to Election / Restriction Filed		1	1	
	Claims		2	3	
	Response to Election / Restriction Filed		4	5	

**Warnings:**

**Information:**

3	Fee Worksheet (PTO-06)	fee-info.pdf	8154	no	2
---	------------------------	--------------	------	----	---

**Warnings:**

**Information:**

<b>Total Files Size (in bytes):</b>			190566		
-------------------------------------	--	--	--------	--	--

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

**New Applications Under 35 U.S.C. 111**

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

**National Stage of an International Application under 35 U.S.C. 371**

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, In due course.

**New International Application Filed with the USPTO as a Receiving Office**

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

ATTORNEY DOCKET NO. 01231.0023U2  
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	)	
JACOBS <i>et al.</i>	)	Art Unit: 1635
Application No. 10/563,728	)	Examiner: Whiteman, Brian A
Int. Filing Date: 08 July 2004	)	Confirmation No. 1957
For: MUTANTS OF VACCINIA VIRUS	)	
AS ONCOLYTIC AGENTS	)	

AMENDMENT AND RESPONSE TO RESTRICTION REQUIREMENT

**Mail Stop Amendment**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

NEEDLE & ROSENBERG, P.C.  
Customer Number 23859

Sir:

This is in response to the Office Action dated March 2, 2007, wherein restriction of the claims of the above-identified application is required. A Request for Extension of time is included herewith.

**Amendments to the Claims** are reflected in the listing of claims which begins on page 2 of this Amendment.

**Remarks** begin on page 4 of this Amendment.

**Amendments to the Claims**

The listing of claims set forth below will replace all prior versions and listings of claims in the application.

1. (Original) A method of inducing lysis of proliferating cancer cells comprising contacting said cells with a vaccinia virus having an inactivating mutation in an interferon resistance gene.
2. (Original) The method of claim 1, wherein the cancer cells are ras-transformed cells.
3. (Original) The method of claim 1, wherein the cancer cells are breast cancer cells or prostate cancer cells.
4. (Original) The method of claim 1, wherein the inactivating mutation is in a gene selected from the group consisting of E3L, K3L, or a combination thereof.
5. (Original) The method of claim 4, wherein the inactivating mutation is selected from the group consisting of a deletion mutation, a substitution mutation, and a missense mutation.
6. (Original) The method of claim 4, wherein the inactivating mutation is in the E3L gene.
7. (Original) The method of claim 6, wherein the mutation is a deletion of the whole E3L gene.
8. (Original) The method of claim 1, wherein the mutant vaccinia virus has a reduced ability to inhibit PKR and increased sensitivity to interferon.
9. (Original) The method of claim 1, wherein said contacting comprises administering a therapeutic amount of the vaccinia virus to a mammal comprising proliferating cancer cells under conditions that permit contact between the vaccinia virus and the proliferating cancer cells.

**ATTORNEY DOCKET NO. 01231.0023U2**  
**Application No. 10/563,728**

10. (Original) The method of claim 9, wherein the administering is selected from the group consisting of intratumoral injection, intravenous injection, and intravascular injection.

Claims 11-16 (Canceled)

**Remarks**

Claims 1-10 are pending. Claims 11-16 have been canceled.

**Restriction Requirement**

The Office Action requires restriction to one of the following two groups of claims:

Group I: Claims 1-10, drawn to a method of using a vaccinia virus having an inactivation mutation in an interferon resistance gene, and

Group II: Claims 11-16, drawn to a vaccinia virus having an inactivation mutation in an interferon resistance gene.

As required in response to the Restriction Requirement, Applicants elect Group I (claims 1-10). In order to facilitate prosecution, claims 11-16 (Group II) have been canceled.

The Office Action also required election of a species for the genes having the inactivation mutation from among E3L, K3L, or a combination thereof. In response, applicants elect for examination of E3L with traverse.

Favorable consideration of claims 1-10 is earnestly solicited.

A Credit Card Payment authorizing payment in the amount of \$60.00, representing the fee for a small entity under 37 C.F.R. § 1.17(a)(1) for a One Month Extension of Time, and a Request for Extension of Time are hereby enclosed. This amount is believed to be correct;

ATTORNEY DOCKET NO. 01231.0023U2  
Application No. 10/563,728

however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

NEEDLE & ROSENBERG, P.C.

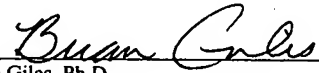


P. Brian Giles, Ph.D.  
Registration No. 57,896

NEEDLE & ROSENBERG, P.C.  
Customer Number 23859  
(678) 420-9300  
(678) 420-9301 (fax)

CERTIFICATE OF EFS-WEB TRANSMISSION UNDER 37 C.F.R. § 1.8

I hereby certify that this correspondence, including any items indicated as attached or included, is being transmitted by EFS-WEB on the date indicated below.

  
P. Brian Giles, Ph.D.

Date 5/2/07



ATTORNEY DOCKET NO. 01231.0023U2  
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	)	
JACOBS <i>et al.</i>	)	Art Unit: 1635
Application No. 10/563,728	)	Examiner: Whiteman, Brian A
Int. Filing Date: 08 July 2004	)	Confirmation No. 1957
For: MUTANTS OF VACCINIA VIRUS	)	
AS ONCOLYTIC AGENTS	)	

REQUEST FOR EXTENSION OF TIME

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

NEEDLE & ROSENBERG, P.C.  
Customer Number 23859

Sir:

It is respectfully requested that an extension of time for the period indicated below be granted in accordance with the provisions of 37 C.F.R. Section 1.136 to take action required in the application identified in the caption, as reflected by the papers submitted herewith:

<input checked="" type="checkbox"/>	One Month	\$120.00	(\$ 60.00)*
<input type="checkbox"/>	Two Months	\$450.00	(\$225.00)*
<input type="checkbox"/>	Three Months	\$1,020.00	(\$510.00)*
<input type="checkbox"/>	Four Months	\$1,590.00	(\$795.00)*
<input type="checkbox"/>	Five Months	\$2,160.00	(\$1,080.00)*

\* Small Entity

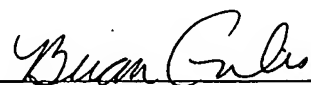
A Credit Card payment in the amount of \$60.00, representing \$60.00 for the Extension of Time fee for a small entity under 37 C.F.R. § 1.17(a)(1) and the Response to Restriction

ATTORNEY DOCKET NO. 01231.0023U2  
Application No. 10/563,723

Requirement are enclosed. This amount is believed to be correct; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,


NEEDLE & ROSENBERG, P.C.

  
P. Brian Giles, Ph.D.  
Registration No. 57,896

NEEDLE & ROSENBERG, P.C.  
Customer Number 23859  
(678) 420-9300  
(678) 420-9301 (fax)

CERTIFICATE OF EFS-WEB TRANSMISSION UNDER 37 C.F.R. § 1.8

I hereby certify that this correspondence, including any items indicated as attached or included, is being transmitted by EFS-WEB on the date indicated below.

  
P. Brian Giles, Ph.D.

Date 5/2/07